IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Robert F. Rioux, et al.

Serial No.: 10/685,744

Filed: October 14, 2003

For: LIQUID INFUSION APPARATUS FOR RADIOFREQUENCY TISSUE ABLATION

Group Art Unit: 3739

Confirmation No. : 6134

Examiner: Toy, Alex B.

APPEAL BRIEF-CFR 41.37

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in furtherance of the Notice of Appeal filed June 15, 2006, and contains the following items in the order indicated below as required by C.F.R. §41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
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V. Summary of Claimed Subject Matter
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I. Real Party in Interest

The real party in interest in this appeal is Scimed Life Systems, Inc., a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-25. Of these, claims 1-16 are pending, and the remaining claims 17-25 have been cancelled. All pending claims stand rejected, leaving no claims allowed. The claims on appeal are claims 1-16.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

In its broadest sense, the invention, as defined in the claims on appeal, is directed to an apparatus for delivering electrical energy to tissue within a patient. The apparatus comprises a tubular member having a lumen extending from the proximal end of the tubular member to the distal end of the tubular member. The apparatus further comprises at least one needle extending from the lumen. The needle(s) has a distal portion that comprises an electrically conductive and porous material (e.g., a sintered stainless steel), thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion of the needle. As a result, the increased perfusion of the electrolytic fluid may enhance

heating of the tissue, thereby providing a larger and more uniform three-dimensional volume of tissue being ablated and/or may reduce the RF delivery time necessary to ablate the tissue. Although it should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of the preferred embodiments in order to aid in further understanding the invention.

Figs. 1 and 2 illustrate the basic embodiment of an apparatus 10 for treating tissue (page 9, lines 2-4). The apparatus 10 generally includes a cannula 12, an array of electrodes 14, and a source of electrical energy 16 and source of conductive fluid 18 coupled to the array of needles 14 (page 9, lines 5-9).

The cannula 12 is an elongate tubular member having a lumen 24 extending from the proximal end 20 to the distal end 22 of the cannula 12 (page 9, lines 10-13). The array of electrodes 14 are deployable in that they may alternately be placed within a collapsed configuration by retracting them within the lumen 24 of the cannula 12 (Fig. 2), and placed within an expanded configuration (Fig. 1) by extending them from the lumen 24 beyond the distal end 22 of the cannula 12 (Fig. 2) (page 11, line 21 to page 12, line 6).

The array of electrodes 14 includes a plurality of elongate needles 30 having sharp or tissue-penetrating distal tips 32 (page 10, lines 11-14). The needles 30 include infusion lumens 34 for delivering a fluid to outlets 36 located in the distal tips 32 of the needles 30 (page 10, lines 14-19). A side port 40, which may be coupled to the source of conductive fluid 18, is in fluid communication with the infusion lumens 34 of the needles 30, so that an electrolytic fluid, such as saline, can be delivered to the needles 30 (page 10, line 19 to page 11, line 4). The needles 30 are also electrically

coupled to the source of electrical energy 16, so that electrical energy can be delivered to the needles 30, thereby creating electrodes (page 13, line 21 to page 14, line 4).

Referring to Figs. 5A and 5B of the specification, the apparatus 10 may be used to treat tissue. For example, the cannula 12, with the electrodes 14 provided in their collapsed configuration within the lumen 24 of the cannula 12, is advanced into a target tissue region 92 of the patient (Fig. 5A) (page 15, lines 9-22). Next, the array of electrodes 14 may be deployed from the distal end 22 of the cannula 12 and placed into the expanded configuration within target tissue region 92 (Fig. 5B)(page 16, line 21 to page 17, line 7). An electrolytic solution, such as saline, is then introduced from the source of electrolytic fluid 14 through the infusion lumens 34 of the needles 30 and into the target region 92 via the outlets 36 (page 17, lines 18). RF energy is then delivered from the RF generator 16 into the target region 92 via the needles 30, whereby the target region 92 is more efficiently ablated due to the presence of the saline within the tissue (page 17, line 19 to page 18, line 7).

VI. Grounds of Rejection to be Revealed on Appeal

A. Whether claims 1-4 and 6-15 are unpatentable under 35 U.S.C. §103 as being obvious over U.S. Patent No. 6,071,280 ("Edwards") in view of U.S. Patent No. 6,241,710 ("VanTassel").

B. Whether claim 5 is unpatentable under 35 U.S.C. §103 as being obvious over Edwards, in view of VanTassel, in further view of U.S. Patent No. 4,512,768 ("Rangaswamy").

C. Whether claim 16 is unpatentable under 35 U.S.C. §103 as being obvious over Edwards, in view of VanTassel, in further view of U.S. Patent No. 6,503,225 ("Kirsch").

VII. Arguments

A. Claims 1-4 and 6-15

Appellant respectfully submits that the Examiner erred in rejecting claims 1-4 and 6-15 under 35 U.S.C. §103 as being obvious over Edwards in view of VanTassel, since VanTassel is neither non-analogous prior art that cannot be combined with Edwards, nor is there any motivation or suggestion in VanTassel or any other cited prior art reference to modify the device of Edwards in a manner that would obviate these claims.

In particular, the Examiner essentially concludes that VanTassel is combinable with Edwards as analogous prior art and provides the necessary suggestion to modify the Edwards device merely because VanTassel, Edwards, and the application are all concerned with delivering fluid from a needle into tissue. Appellant respectfully submits that this showing simply does not support a prima facie case of obviousness.

While Edwards and the application do disclose a radio frequency (RF) ablation probe with needle electrodes capable of perfusing an electrolytic solution, VanTassel discloses a porous drug delivery needle for injecting a medicament, which is a completely different application than therapeutic RF energy delivery, and provides absolutely no teaching or suggestion that the use of a porous needle can be used in an RF application, e.g., to enhance the ablation of tissue via the perfusion of an electrolytic solution. Because the teachings of VanTassel are so different from those of Edwards and the application, VanTassel cannot be considered analogous prior art to the claimed

invention, and further fails to suggest that the Edwards device be modified in any manner. Indeed, one could only conclude that the Examiner improperly used the teachings of the application to make the connection between these two disparate references.

1. VanTassel Not Analogous Prior Art

In concluding that independent claims 1 and 10 are obvious, the Examiner combined the porous hypodermic needle disclosed in VanTassel with the electrosurgical probe of Edwards (see page 4, lines 14-22 of Office Action, dated October 17, 2006). However, VanTassel is not analogous prior art that can be properly used in combination with Edwards.

The M.P.E.P. states:

> The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." (M.P.E.P. §2141.01(a))(citations omitted)(emphasis added).

VanTassel is neither in the field of the inventors' endeavor nor is it reasonably pertinent to the particular problem with which the inventors were concerned. That is, the field of the inventors' endeavor is the ablative treatment of tumors (see page 1, lines 5-8), whereas the field that VanTassel is concerned with is the injection of medicaments into tissue (see col. 1, lines 5-7). Furthermore, the particular problem with which the inventors were concerned with was making therapeutic ablations more efficient (see page 2, lines 7-19), whereas the particular problem solved by VanTassel was providing

a means for microinjecting controlled amounts of injectate to minimize leakage otherwise due to the rapid transfer of fluid (col. 2, lines 24-32). Thus, it can be appreciated that Appellant's and VanTassel's endeavors are in completely different fields and are concerned with entirely different problems. As such, VanTassel cannot be properly combined with Edwards to form a basis for rejecting claims 1 and 10.

However, rather than performing the necessary analysis for determining whether VanTassel is truly an analogous prior art reference, the Examiner has merely stated that VanTassel is analogous to the claimed invention because both are concerned with delivering fluid from a needle into tissue (see page 10, lines 9-11 of Final Office Action, dated March 15, 2006). However, the mere fact that a prior art reference and a claimed invention have commonalities is irrelevant to the determination of whether such prior art reference is analogous prior art. To find otherwise would completely eviscerate the requirement that a prior art reference be analogous for it to be considered in an obviousness rejection, since, presumably, commonalities can always be found between an invention and a prior art reference used to reject the invention. What is relevant is whether the prior art is in the field of inventors' endeavor or reasonably pertinent to the particular problem with which the inventors were concerned. Because the Examiner completely failed to provide any analysis with regard to this, a prima facie case has not been made that VanTassel is an analogous prior art reference.

2. Any Suggestion to Modify Edwards in View of VanTassel is Lacking

Even if VanTassel were somehow considered to be analogous prior art, there is no suggestion in VanTassel to modify the Edwards ablation device in a manner that would render independent claims 1 and 10 obvious.

The MPEP provides:

> Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." MPEP §2143.01(I.)(emphasis added).

The Examiner has not gone through this analysis, and has merely concluded that because VanTassel teaches a needle composed of a porous material for delivering fluid, it would have been obvious to one of ordinary skill in the art to modify the Edwards device to have a sintered porous needle to provide an alternative way of allowing fluid to flow through the walls of the needle (see page 4, lines 14-22). The Examiner further concluded that the suggestion or teaching to modify the Edwards device in this manner is provided by the prior art, because "using the knowledge generally available to one of ordinary skill in the art, it would have been obvious to modify Edwards in view of VanTassel because both references use pores in a needle shaft to deliver fluid into tissue." (See page 10, lines 17-20 of Final Office Action, dated March 15, 2006).

However, the fact that both Edwards and VanTassel deliver fluid through openings in a needle does not provide any suggestion that the Edwards ablation needle should be modified to include a porous material in the manner described in VanTassel. The fact that two prior art references have commonalities is not the proper inquiry in determining whether the prior art references can be properly combined. The Examiner has not provided any reason why VanTassel would suggest, explicitly or implicitly, to one of ordinary skill in the art to make such a modification to the Edwards device. As

required by the MPEP, a proper analysis requires the Examiner to determine what VanTassel teaches as a whole, including the problem to be solved, and whether those teachings can be fairly applied to Edwards.

However, because the teachings of VanTassel are irrelevant to tissue ablation, they cannot be fairly applied to Edwards. That is, VanTassel teaches the use of a porous hypodermic needle in order to microinject medicament into tissue, so that rapid fluid transfer is prevented (see col. 2, lines 18-32), and teaches nothing about RF tissue ablation or the effects of electrically conductive fluid perfusion on RF tissue ablation. There is simply no suggestion from this that electrically conductive fluid can be perfused from an RF ablation probe with porous needle electrodes to increase the size of the resulting ablation or provide any other advantage associated with RF ablation probes, such as increasing the echogenicity of the ablation probe (see page 28, line 7 to page 29, line 2).

Significantly, in determining whether such suggestion or motivation exists in the prior art, the Examiner cannot benefit from impermissible hindsight vision afforded by the claimed invention. In particular:

> Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (M.P.E.P. §2142) (emphasis added).

Because there is no suggestion in VanTassel to modify an ablation device, Appellant believes that one can only conclude that the Examiner has improperly used Appellant's specification to provide this suggestion. Without Appellant's specification,

the Examiner is left with Edwards disclosing the need for an ablation device with infusion capabilities to improve the resulting tissue ablation, and VanTassel disclosing a hypodermic needle composed of a porous material to deliver a medicament in a controlled manner. There is simply no suggestion in VanTassel to modify the perfusion capability of ablation devices to improve tissue ablation.

Thus, Appellant submit that independent claims 1 and 10, as well as the claims depending therefrom (claims 2-4, 6-9, and 11-15), are not obvious over any proper combination of Edwards and VanTassel. As such, Appellant respectfully requests this Board to overturn the Examiner's §103 rejections of these claims.

B. Claim 5

Appellant respectfully submits that the Examiner erred in rejecting claim 5 under 35 U.S.C. §103 as being obvious over Edwards, in view of VanTassel, in further view of Rangaswamy, because VanTassel, as a non-analogous prior art reference, was improperly used to reject independent claim 1 from which claim 5 depends. In addition, notwithstanding VanTassel's status as non-analogous prior art, there is no suggestion in the prior art to modify the Edwards device in view of VanTassel, as discussed above, and Rangaswamy does not supplement the failed teachings of Edwards and VanTassel. Thus, Appellant respectfully believes that claim 5 is not obvious over any proper combination of Edwards, VanTassel, and Rangaswamy. As such, Appellant respectfully requests this Board to overturn the Examiner's §103 rejection of this claim.

C. Claim 16

Appellant respectfully submits that the Examiner erred in rejecting claim 5 under 35 U.S.C. §103 as being obvious over Edwards, in view of VanTassel, in further view of

Kirsch, because VanTassel, as a non-analogous prior art reference, was improperly used to reject independent claim 10 from which claim 16 depends. In addition, notwithstanding VanTassel's status as non-analogous prior art, there is no suggestion in the prior art to modify the Edwards device in view of VanTassel, as discussed above, and Kirsch does not supplement the failed teachings of Edwards and VanTassel. Thus, Appellant respectfully believes that claim 16 is not obvious over any proper combination of Edwards, VanTassel, and Kirsch. As such, Appellant respectfully requests this Board to overturn the Examiner's §103 rejection of this claim.

Respectfully submitted,

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VIII. Appendix of Claims Involved in the Appeal

1. An apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member comprising a proximal end, a distal end having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end; and

a needle comprising a distal portion extending at least partially from the lumen and terminating in a tissue-piercing distal tip, the distal portion comprising an electrically conductive and porous material, thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion.

2. The apparatus of claim 1, wherein the distal portion comprises sintered stainless steel.

3. The apparatus of claim 1, wherein the needle comprises a needle lumen extending from a proximal end of the needle to the distal portion.

4. The apparatus of claim 3, further comprising a source of electrolytic fluid coupled to the needle lumen for delivering electrolytic fluid to the distal portion of the needle.

5. The apparatus of claim 1, wherein the entire needle comprises porous material.

6. The apparatus of claim 1, wherein the needle is movable relative to the tubular member for at least one of retracting the distal portion into the tubular member

and deploying the distal portion from the tubular member.

7. The apparatus of claim 1, wherein the tubular member comprises an electrically insulating sleeve.

8. The apparatus of claim 1, further comprising a plurality of needles extendable from the lumen beyond the distal end of the tubular member, each needle comprising a distal tip for penetrating tissue.

9. The apparatus of claim 8, wherein each of the plurality of needles comprises a distal portion comprising an electrically conductive and porous material, thereby providing an array of porous electrodes through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portions of the array of electrodes.

10. An apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member comprising a proximal end, a distal end having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end of the tubular member; and

an array of needles extendable from the lumen beyond the distal end of the tubular member, each needle comprising a distal tip for penetrating tissue, at least one needle comprising a distal portion comprising an electrically conductive and porous material, thereby providing a porous electrode through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portion.

11. The apparatus of claim 10, wherein the needles are movable from a

retracted configuration within the lumen to an extended configuration wherein distal portions of the needles extend beyond the distal end of the tubular member.

12. The apparatus of claim 11, wherein a plurality of the needles have distal tips that extend different axial and radial distances from one another in the extended configuration.

13. The apparatus of claim 11, wherein a distal portion of a plurality of the needles comprises an electrically conductive and porous material defining an electrode.

14. The apparatus of claim 10, further comprising a source of conductive fluid connected to the infusion lumen of each needle comprising an infusion lumen.

15. The apparatus of claim 14, further comprising a hub proximal to the distal end of the tubular member, the hub comprising a port connected to the source of conductive fluid, the hub communicating with each infusion lumen for delivering conductive fluid from the source of conductive fluid to each porous electrode.

16. The apparatus of claim 14, further comprising a float valve connected to the source of conductive fluid for removing gases from conductive fluid being delivered from the source of conductive fluid to each porous electrode.

IX. Evidence Appendix

1. U.S. Patent No. 6,071,280. Originally cited by Examiner in Office Action, dated October 17, 2005.

2. U.S. Patent No. 6,241,710. Originally cited by Examiner in Office Action, dated October 17, 2005.

3. U.S. Patent No. 4,512,768. Originally cited by Examiner in Office Action, dated October 17, 2005

4. U.S. Patent No. 6,503,225. Originally cited by Examiner in Office Action, dated October 17, 2005.

X. Related Proceedings Appendix

None.